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(54) **Knee joint prosthesis articular surface**

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EP-A- 0 442 330 FR-A- 2 145 957
US-A- 4 034 418 US-A- 4 340 978
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Description

The present invention relates to knee joint prostheses, and more particularly, to an improved implantable knee joint prosthesis including femoral and tibial components with improved articular surface geometries that allow flexion of the knee about an inclined flexion axis with regard to horizontal, the flexion axis being higher toward the middle of the body and lower toward the outside edge of the body.

In the reconstruction of the anatomical knee joint by total or partial replacement with a prosthetic joint, femoral and tibial prosthetic components provide a knee joint prosthesis in which the articulating or contacting surfaces of the components operate to provide a functioning knee joint.

At the present time, most knee prostheses provide for anteroposterior rotation about a horizontal flexion axis in order to allow movement similar to the anatomical knee joint with the tendons and ligaments of the joint imparting stability and the components affording a certain degree of stability.

Human joints are complex systems which serve a number of functions. Perhaps the most important function is to provide a means of moving body parts for locomotive purposes. The motion provided by most human joints is not simple rotation or translation, but a complex combination of movements.

Perhaps the best known joint with complex motion is the knee. The knee is capable of translation and rotation about three orthogonal axes. Motion is controlled by the collective actions of the articular surface geometries and forces applied to the joint.

Joint replacement devices utilized for pain relief and restoration of function seek to restore normal motion. However, in all cases known to the applicants, the motion allowed by the articular surface geometries (which have been simplified to readily facilitate manufacture and to minimize wear of the articulating components) is abnormally simple. As a result, a "kinematic conflict" may develop at the articular surfaces because the motion allowed by the implants may not be compatible with their relative positions as dictated by external forces.

A kinematic conflict may lead to excessive stresses between the articulating components, leading to destruction of one or both surfaces. Destruction of the surfaces will result in high wear rates, the release of wear debris into the joint, and undesirable tissue reactions. The symptoms are likely to be sufficiently severe to require surgical removal and replacement of the implants, with all of the inherent risks and injuries to the patient.

The above-described problem is particularly true of the reconstructed knee joint in movements from full extension to about twenty degrees of flexion during load bearing activities such as walking. During these activities the normal femur externally rotates about five to fifteen degrees (5° - 15°) on the surface of the tibia as the knee flexes twenty degrees (20°). All total knee replacements known to the applicants will not allow this motion to occur without the aforementioned kinematic conflict and negative consequences.

Prior art approaches to this problem include utilizing incongruent articular surface geometries (except for line contact). In these designs, congruence of the articular surfaces is limited to one plane (usually the frontal plane) and results in a line contact between the components. The elasticity of one of the articulating members (usually a polymer tibial component) allows the line contact to expand to an area contact if contact forces are sufficiently large. However, the area contact due to elastic deformation is not sufficient to protect the polymer from excessive stresses and the resulting creep and wear phenomena reported in the literature.

Geometries of this type are advantageous in that they allow relative internal/external rotations of the components without large external forces being applied. However, the contact area between the components diminishes further under these circumstances because the congruent profiles are no longer aligned.

Another approach to this problem has been to simply ignore it, by configuring the articular surface geometries for an area contact and restricting congruent motion to one plane (i.e. flexion and extension only). This approach is advantageous in the sense that it maximizes contact area in pure flexion/extension movements, thus should minimize creep and wear of the polymer.

Designs of this type will not allow internal/external rotation during flexion and extension without substantial effort and stresses between the articulating components. As in the former case, excessive stresses lead to wear and creep of the polymer component and early failure of the joint replacement.

There is yet another approach to this problem known as the meniscal bearing prosthesis. Meniscal bearing prostheses feature an area contact at the articular interface because of congruent surfaces (similar to the Tricon knee). To obviate the problem of excessive constraint inherent in these designs, the polymer insert(s) is designed to be mobile on the surface of a metal plate which is attached to bone. The mobility of the insert(s) helps to avoid a kinematic conflict at the articular interface by allowing the bones to adjust their relative positions according to external forces while maintaining an area contact at the articular interface.

Examples of meniscal bearing designs can be found for example in the oxford knee (European patent 327387-A) and New Jersey Knee (U.S. patents 4,309,778, 4,340,978, and 4,470,158). These designs have several disadvantages. First, the polymer inserts have a tendency to dislocate, requiring surgical intervention for replacement. Second, if all ligamentous structures are not preserved and functional, these designs will not provide the stability required for good function and patient confidence. Additionally, the New Jersey design, while featuring mobile inserts, does not allow the desired motion, because internal/external rotations of the inserts are centered on the metal tibial tray, and not lateral to the center. This inconsistency may lead to a kinematic conflict (especially if all ligamentous structures are preserved and functional).

An example of another prior art type of knee joint presently utilized is disclosed eg. in U.S. Patent No. 4,298,992, issued on November 10, 1981 for a "Posteriorly Stabilized Total Knee Joint Prosthesis" wherein there is included a femoral component utilizing a pair of laterally spaced apart condylar portions, each of which having an external surface convexly curved to match generally the lateral profile of the anatomical femoral condyle.

U.S. Patent No. 4,298,992 further discloses a tibial component and a platform portion including spaced apart concavities for receiving each of the condylar portions of the femoral component. The post extends from the tibial plateau into the intracondylar recess of the femoral component so that upon full flexion of the joint, the knee joint is stabilized between the tibial post and femoral recess. The '992 patent addresses the prevention of translocation of the knee during flexion.

Another example of a prior art knee joint is described in US -A- 4892547 which discloses a partially stabilized knee joint prosthesis which includes a femoral component and a tibial component. The femoral component has spaced-apart condylar bearing portions, anterior and posterior intercondylar portions, and an intercondylar opening defined by edges of the condylar bearing portions and the anterior and posterior intercondylar portions. The tibial component has bearing surfaces for supporting the condylar bearing portions of the femoral component, and a relatively low intercondylar eminence between the bearing surfaces.

The present invention seeks to provide tibial and femoral components with improved articular surface geometries which would enable the tibia to rotate with respect to the femur.

An object of the invention is to create an artificial joint articular surface geometry which will allow internal/external rotations of the joint during flexion/extension movements, while preserving a higher degree of congruence between the articulating surfaces than that allowed by conventional joint replacements.

By allowing combinations of movements with a high degree of congruence between articulating components, contact stresses between components will be reduced, resulting in less creep and wear (ceteris paribus).

The femoral component and tibial components are designed to articulate with one another during normal movements of the knee. The motion which typically occurs during the first twenty degrees of flexion includes up to fifteen degrees (15°) of internal rotation of the tibial component. This combination of flexion and internal rotation with substantially congruent surface area contact between components is facilitated by the special articular surface geometries.

The tibial surface is created by swinging a profile about an axis inclined at an angle between ten and fifty degrees (preferably about thirty-six degrees) with respect to the horizontal reference plane. The inclined axis passes through the horizontal reference plane at a position lateral to the center of the knee. The profile is swept in anterior and posterior directions from the starting position through a sufficiently large arc to completely cover the surface of the largest tibial component required. In the lateral compartment, the profile may not be swept anteriorly about the inclined axis, depending upon the need to match the shape with the femoral component. This change will not affect the kinematics of the tibiofemoral articulation.

The femoral articulating surface is created in a similar manner. A profile is swept about the same inclined axis as with the tibial surface. The profile is swept in anterior and posterior directions through a sufficiently large arc to provide for substantially congruent contact between the femoral and tibial surfaces through the first twenty to thirty degrees of flexion of the femoral component. In the lateral compartment, the profile may not be swept anteriorly about the inclined axis, depending upon the need to match the shape with the tibial component. This change will not affect the kinematics of the tibiofemoral articulation.

For flexion greater than twenty degrees, the posterior condyles of the femoral component begin to articulate with the tibial surface. During this motion, the contact is a small surface area contact, due to the geometries and elasticities of the contacting surfaces. Flexion of the femoral component beyond twenty degrees occurs about an axis which is more or less parallel to the posterior condylar axis.

Because of the inclined axis for the first twenty degrees of flexion, the surfaces of the tibial and femoral components can maintain a large surface area of contact, without a kinematic conflict. The large area of contact will result in lower contact stresses and, therefore reduce creep and wear of the articular surfaces. Reducing damage will extend the life of the joint replacement and reduce the likelihood that revision

surgery will be necessary. This benefit is realized without a compromise in stability (as in meniscal bearing designs), allowing the articular geometry to be used in knees where one or both cruciate ligaments are absent or non-functional.

Therefore, it is an object of the present invention to provide an improved knee prosthesis including tibial and femoral components with improved articulating surface geometries.

It is still another object of preferred embodiments of the present invention to provide a knee joint prosthesis wherein the femoral and tibial components provide improved articular surface geometries that allows rotation (as much as fifteen degrees) of one component with respect to the other about an inclined flexion axis. It is still a further object of preferred embodiments of the present invention to provide a total knee joint prosthesis which includes improved articular surface geometries wherein articular surfaces are formed by rotating a knee prosthesis profile about an inclined axis through a preferred angle of between twenty and forty degrees (20° - 40°) of rotation to create an articular surface which allows the tibial and femoral components to rotate about an inclined flexion axis while maximizing contact area therebetween to lower stresses and prolong prostheses life. The profile, however, could be rotated through an angle of between one and one hundred twenty degrees (1° - 120°), through twenty to forty degrees (20° - 40°) is preferred.

According to the present invention there is provided a knee replacement prosthesis comprising:

- a) a tibial component;
- b) a femoral component that articulates against the tibial component; characterized in that
- c) the tibial and femoral components are capable of flexing about a flexion axis that reaches an inclination of from ten degrees (10°) to fifty degrees (50°) with respect to a line that is tangent to the distal femoral condyles in the frontal plane, while maintaining congruent contact.

Also according to the present invention there is provided a knee joint prosthesis comprising:

- a) a tibial component with a tibial articulating surface;
- b) a femoral component with a femoral articulating surface;
- c) a means for attaching the tibial component to the patient's tibia;
- d) means for attaching the femoral component to the patient's femur; characterized in that
- e) the tibial and femoral components being capable of flexing about a flexion axis that reaches an inclination of from ten degrees (10°) to fifty degrees (50°) with respect to a line that is tangent to the distal femoral condyles in the frontal plane; and
- f) wherein substantial internal rotation of the tibial component is enabled with respect to the femoral component during flexion, and with substantial congruent area contact maintained between the tibial and femoral articulating surfaces.

The invention will now be further described by way of example with reference to the following detailed description taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein:

Figure 1 is a side view of the preferred embodiment of the apparatus of the present invention in full extension position;

FIGURE 2 is a top view of the preferred embodiment of the apparatus of the present invention in full extension position;

FIGURE 3 is a front view of the preferred embodiment of the apparatus of the present invention in full extension position;

FIGURE 4 is a side view of the preferred embodiment of the apparatus of the present invention on a twenty degree (20°) flexion position;

FIGURE 5 is a front view of the preferred embodiment of the apparatus of the present invention in ninety degree flexion position;

FIGURE 6 is a side view of the preferred embodiment of the apparatus of the present invention in a ninety degree (90°) flexion position;

FIGURE 7 is a perspective schematic view of the preferred embodiment of the apparatus of the present invention illustrating generation of the tibial articular surface for a bicompartamental knee prosthesis;

FIGURE 8 is a perspective schematic view of the preferred embodiment of the apparatus of the present invention illustrating the femoral articular surface for a bicompartamental knee prosthesis;

FIGURE 9 is a perspective schematic view of the preferred embodiment of the apparatus of the present invention illustrating generation of the femoral articular surface for a unicompartmental knee prosthesis; and

FIGURE 10 is a perspective schematic view of the preferred embodiment of the apparatus of the present invention illustrating generation of the tibial articular surface for a unicompartmental knee prosthesis.

Referring to the drawings, the preferred embodiment of the knee joint prosthesis of the present invention is illustrated in the figures by the numeral 10. Knee prosthesis 10 includes a tibial component 10-A and a femoral component 10-B. The tibial component 10-A has an upper most tibial articular surface 11 which bears against a femoral articular surface 21 of the femoral component 10-B.

In figure 7, the tibial articular surface 11 is illustrated for a tibial component 10-A having a bicompart-
mental or two condylar surface construction. Figure 7 illustrates a generation of the tibial articular surface 11
using a horizontal reference plane 12 defined by the lines 12-A, 12-B. The line 13 represents an inclined
axis, inclined with respect to the horizontal plane 12 by a measure of for example thirty degrees (30°). The
inclined axis is inclined at an angle of between ten and fifty degrees (10-50°).

In figure 7, the medial 14 and lateral 15 side of the patient's knee is shown for each generation of the
tibial articular surface which is illustrated by the three rotational paths 18, 19 and 20. In the left hand side of
figure 7, an initial rotational path 18 is shown with a single curved line 11-A representing the tibial articular
surface profile. While the profile 11-A consists of three tangent curves, the profile may take other forms,
such as two straight lines connected by one or more curves or straight lines (i.e. the form of the profile itself
is not critical, as long as it meets other general requirements for a knee prosthesis). In the middle of figure
7, the profile 11-A has been rotated through a measure of approximately forty degrees (40°) so that a
plurality of lines 11-A represent a generation of the surface 11 about the axis 13. In the right hand side of
figure 7, the completed articular surface 11 is shown surrounded by the peripheral edge 11-B of the tibial
component 10-A. It should be understood that the tibial component 10-A could for example be of a polymer
material and of a desired outer peripheral shape 11B and of a desired thickness.

In figure 8, the femoral articular surface 21 is illustrated as is the method of generating the femoral
articular surface 21. In figure 8, the horizontal plane 22 is defined by the perpendicular lines 22A, 22B.
Inclined axis 23 defines an angle of between 10 and fifty degrees with respect to horizontal plane 22 and
represents the axis about which the profile line 11B is rotated as represented by the rotational paths 28, 29,
and 30.

The profile 11B represents a profile for forming a bicompartmental knee or two condylar knee
prosthesis. In the left hand side of figure 8, the path of rotation 28 is firstly illustrated with regard to the
single line profile 11B. In figure 8, the profile 11B has been rotated through a measure of approximately
forty degrees (40°) forming the articular surface 21. In the right hand side of figure 8, the tibiofemoral
articular surface 21 has been completed, by the addition of a portion 32 posteriorly of the line 31-31, and
not a portion of the surface 21 generated by rotating the profile 11B about the axis 23. In figures 9 and 10,
tibial and femoral articular surfaces respectively are shown, to illustrate the present invention in a single
compartmental knee prosthesis. In figure 9, the tibial articular surface 33 is illustrated while in figure 10, the
single condylar femoral surface 35 is illustrated.

PARTS LIST

	PART NUMBER	DESCRIPTION
5	10	knee prosthesis
	11	tibial articular surface
	12	horizontal line
	13	inclined axis
	14	medial side of knee
10	15	lateral side of knee
	16	anterior side of knee
	17	posterior side of knee
	18	rotational path, initial
	19	rotational path, middle
	20	rotational path, complete
15	21	femoral articular surface
	22	horizontal line
	23	inclined axis
	24	medial side
	25	lateral side
	26	anterior side
20	27	posterior side
	28	rotational path
	29	rotational path
	30	rotational path
	31	single condylar tibial surface
25	32	single condylar femoral surface

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

Claims

1. A knee replacement prosthesis (10) comprising:
 - a) a tibial component (10-A);
 - b) a femoral component (10-B) that articulates against the tibial component (10-A); characterized in that
 - c) the tibial (10-A) and femoral (10-B) components are capable of flexing about a flexion axis that reaches an inclination of from ten degrees (10°) to fifty degrees (50°) with respect to a line that is tangent to the distal femoral condyles in the frontal plane, while maintaining congruent contact.
2. A prosthesis as claimed in claim 1 wherein the femoral component (10-B) is capable of external rotation with respect to the tibial component (10-A), at least during the first few degrees of flexion from a beginning fully extending position.
3. A prosthesis as claimed in claim 1 or 2, wherein the flexion axis is higher toward the middle portion of the users body and lower toward the side portion of the users body.
4. A prosthesis as claimed in any one of the preceding claims, wherein the tibial component (10-A) includes a single condylar articulating surface.
5. A prosthesis as claimed in any one of the preceding claims, wherein the femoral component (10-B) includes a single condylar articulating surface.
6. A prosthesis as claimed in any one of claims 1 to 4, wherein the tibial component (10-A) has a pair of spaced apart condylar articulating surfaces.

7. A prosthesis as claimed in any one of claims 1 to 4 or 6, wherein the femoral component (10-B) has a pair of spaced apart condylar articulating surfaces.
8. A prosthesis as claimed in any one of the preceding claims, wherein the condylar articulating surface
5 can be generated by rotating a curved line profile about an inclined axis that is inclined between ten (10) and fifty (50) degrees with respect to horizontal.
9. A prosthesis as claimed in claim 8, wherein the curved profile is rotated about the inclined axis by a measure between one and one hundred twenty degrees (1° - 120°).
10. A knee joint prosthesis comprising:
 - a) a tibial component (10-A) with a tibial articulating surface (11);
 - b) a femoral component (10-B) with a femoral articulating surface (21);
 - c) a means for attaching the tibial component to the patient's tibia;
 - 15 d) means for attaching the femoral component to the patient's femur; characterized in that
 - e) the tibial and femoral components (10-A, 10-B) being capable of flexing about a flexion axis that reaches an inclination of from ten degrees (10°) to fifty degrees (50°) with respect to a line that is tangent to the distal femoral condyles in the frontal plane; and
 - 20 f) wherein substantial internal rotation of the tibial component (10-A) is enabled with respect to the femoral component (10-B) during flexion, and with substantial congruent area contact maintained between the tibial and femoral articulating surfaces (11,21).

Patentansprüche

- 25 1. Knie-Ersatzprothese (10) mit
 - a) einer tibialen Komponente (10A),
 - b) einer femoralen Komponente (10B), welche an der tibialen Komponente (10A) gelenkig anliegt* dadurch gekennzeichnet, daß
 - 30 c) die tibiale Komponente und die femorale Komponente (10B) in der Lage sind, um eine Flexionsachse zu flektieren, die eine Neigung von 10 Grad (10°) bis 50 Grad (50°) in bezug auf eine Linie erreicht, die tangential zu den distalen femoralen Gelenkknorren in der Frontalebene ist, wobei eine kongruente Berührung aufrechterhalten wird.
2. Prothese nach Anspruch 1, bei welcher die femorale Komponente (10B) zu externer Rotation in bezug
35 auf die tibiale Komponente (10A) wenigstens während der ersten wenigen Flexionsgrade von einer zu Beginn voll gestreckten Position in der Lage ist.
3. Prothese nach Anspruch 1 oder 2, bei welcher die Flexionsachse höher in Richtung auf den mittleren Teil des Körpers des Benutzers und niedriger in Richtung auf den seitlichen Teil des Körpers des
40 Benutzers ist.
4. Prothese nach einem der vorhergehenden Ansprüche, bei welcher die tibiale Komponente (10A) eine einzige kondyläre Gelenkfläche aufweist.
- 45 5. Prothese nach einem der vorhergehenden Ansprüche, bei welcher die femorale Komponente (10B) eine einzige kondyläre Gelenkfläche einschließt.
6. Prothese nach einem der vorhergehenden Ansprüche 1-4, bei welcher die tibiale Komponente (10A) ein
50 Paar von einem Abstand voneinander aufweisenden kondylären Gelenkflächen aufweist.
7. Prothese nach einem der vorhergehenden Ansprüche 1-4 oder 6, bei welcher die femorale Komponente (10B) ein Paar von einem Abstand Voneinander aufweisenden kondylären Gelenkflächen aufweist.
8. Prothese nach einem der vorhergehenden Ansprüche, bei welcher die kondyläre Gelenkfläche durch
55 Rotieren eines gekrümmten Linienprofils um eine geneigte Achse erzeugt werden kann, die zwischen zehn (10) und fünfzig (50) Grad in bezug auf die Horizontale geneigt ist.

9. Prothese nach Anspruch 8, bei welcher das gekrümmte Profil um die geneigte Achse um ein Maß zwischen einem und einhundertzwanzig Grad (1° - 120°) rotiert wird.

10. Kniegelenkprothese mit

- 5 a) einer tibialen Komponente (10A) mit einer tibialen Gelenkfläche (11),
- b) einer femoralen Komponente (10B) mit einer femoralen Gelenkfläche (21),
- c) einem Mittel zum Anbringen der tibialen Komponente an der Tibia des Patienten,
- d) Mittel zum Anbringen der femoralen Komponente an dem Femur des Patienten, dadurch gekennzeichnet, daß
- 10 e) die tibiale Komponente (10A) und die femorale Komponente (10B) in der Lage sind, um eine Flexionsachse zu flektieren, die eine Neigung von zehn Grad (10°) bis fünfzig Grad (50°) in bezug auf eine Linie erreicht, die tangential an den distalen femoralen Gelenkknorren in der Frontalebene ist und
- f) bei welcher eine erhebliche interne Rotation der tibialen Komponente (10A) in bezug auf die femorale Komponente (10B) während der Flexion ermöglicht wird und bei Aufrechterhaltung einer erheblichen kongruenten Flächenberührung zwischen den tibialen und femoralen Gelenkflächen (11, 21).
- 15

Revendications

- 20 1. Prothèse de genou (10) comprenant :
 - a) un composant tibial (10-A);
 - b) un composant fémoral (10-B) qui s'articule sur le composant tibial (10-A);
 - caractérisée en ce que
 - 25 c) le composant tibial (10-A) et le composant fémoral (10-B) peuvent fléchir autour d'un axe de flexion, qui atteint une inclinaison de dix degrés (10°) à cinquante degrés (50°) par rapport à une droite qui est tangente aux condyles fémoraux distals dans le plan frontal, tout en maintenant un contact congruent.
- 30 2. Prothèse selon la revendication 1, dans laquelle le composant fémoral (10-B) peut tourner extérieurement par rapport au composant tibial (10-A), au moins pendant les premiers degrés de flexion à partir d'une position d'extension complète.
- 35 3. Prothèse selon la revendication 1 ou 2, dans laquelle l'axe de flexion est plus élevé en direction de la partie médiane du corps de l'utilisateur et est plus bas en direction de la partie du côté du corps de l'utilisateur.
- 40 4. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle le composant tibial (10-A) comprend une seule surface d'articulation condyloire.
- 5. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle le composant fémoral (10-B) comprend une seule surface d'articulation condyloire.
- 45 6. Prothèse selon l'une quelconque des revendications 1 à 4, dans laquelle le composant tibial (10-A) possède un couple de surfaces espacées d'articulation condyloire.
- 7. Prothèse selon l'une quelconque des revendications 1 à 4 ou 6, dans laquelle le composant fémoral (10-B) possède un couple de surfaces espacées d'articulation condyloire.
- 50 8. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle la surface d'articulation condyloire peut être produite moyennant la rotation d'un profil de ligne courbe autour d'un axe incliné qui est incliné d'un angle compris entre dix (10) et cinquante (50) degrés par rapport à l'horizontale.
- 55 9. Prothèse selon l'une quelconque des revendications 8, dans laquelle le profil courbe est pivoté autour de l'axe incliné, d'une valeur comprise entre un degré et cent-vingt degrés (1° - 120°).
- 10. Prothèse d'articulation de genou comprenant :
 - a) un composant tibial (10-A) pourvu d'une surface d'articulation de tibia (11);

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b) un composant fémoral (10-B) comportant une surface d'articulation fémorale (21);

c) des moyens pour fixer le composant tibial au tibia du patient;

d) des moyens pour fixer le composant fémoral au fémur du patient;

caractérisée en ce que

- 5 e) les composants tibial et fémoral (10-A, 10-B) pouvant fléchir autour d'un axe de flexion qui atteint une inclinaison comprise entre dix degrés (10°) et cinquante degrés (50°) par rapport à une droite qui est tangente aux condyles fémoraux distals dans le plan frontal; et
- 10 f) une rotation interne substantielle du composant tibial (10-A) est permise par rapport au composant fémoral (10-B) pendant la flexion, et un contact superficiel congruent substantiel étant maintenu entre les surfaces d'articulation (11-21) du tibia et du fémur.
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- 20
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FIG. 1

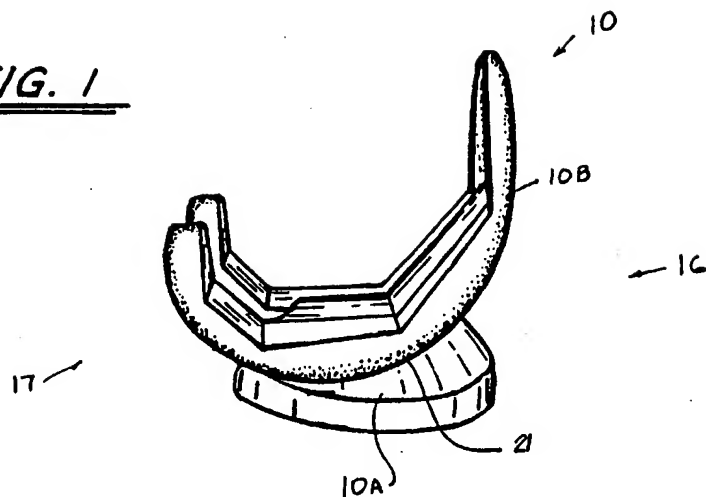


FIG. 2

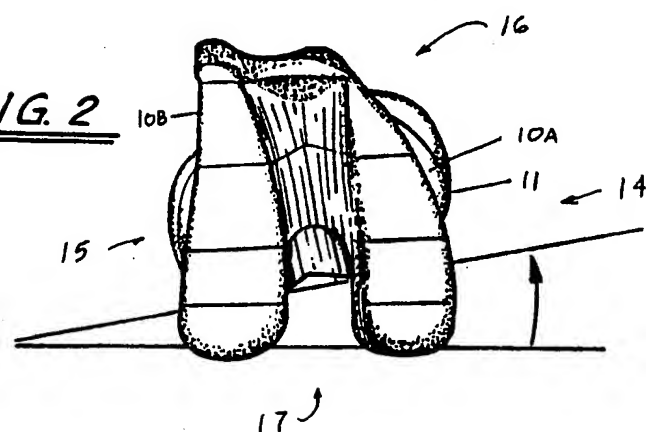
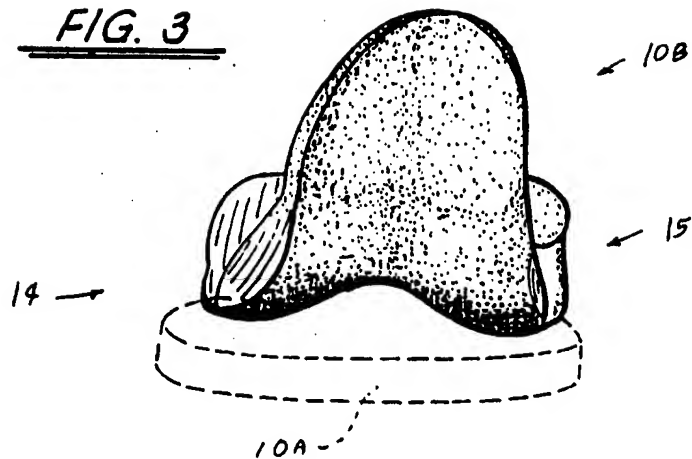
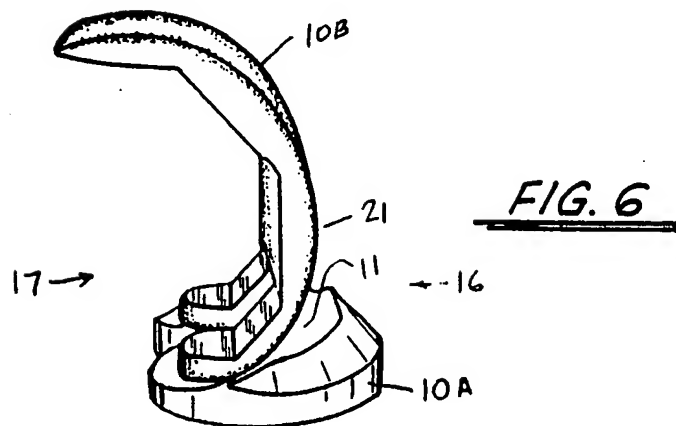
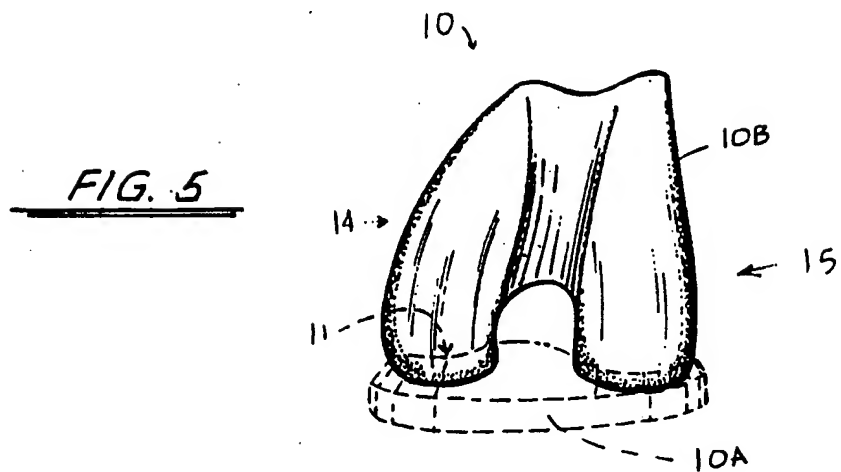
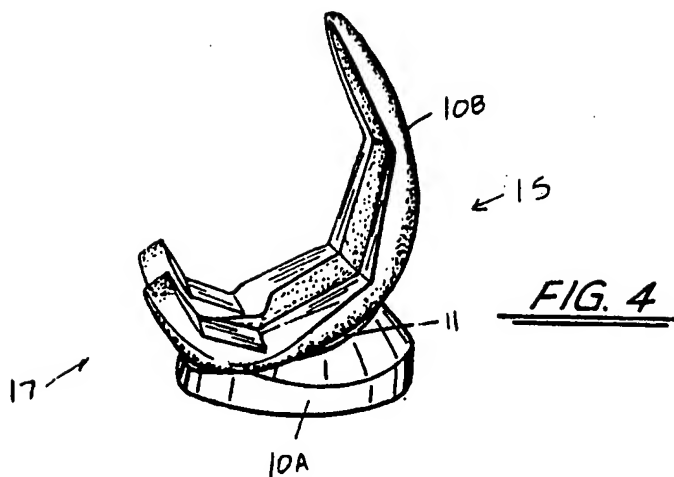


FIG. 3





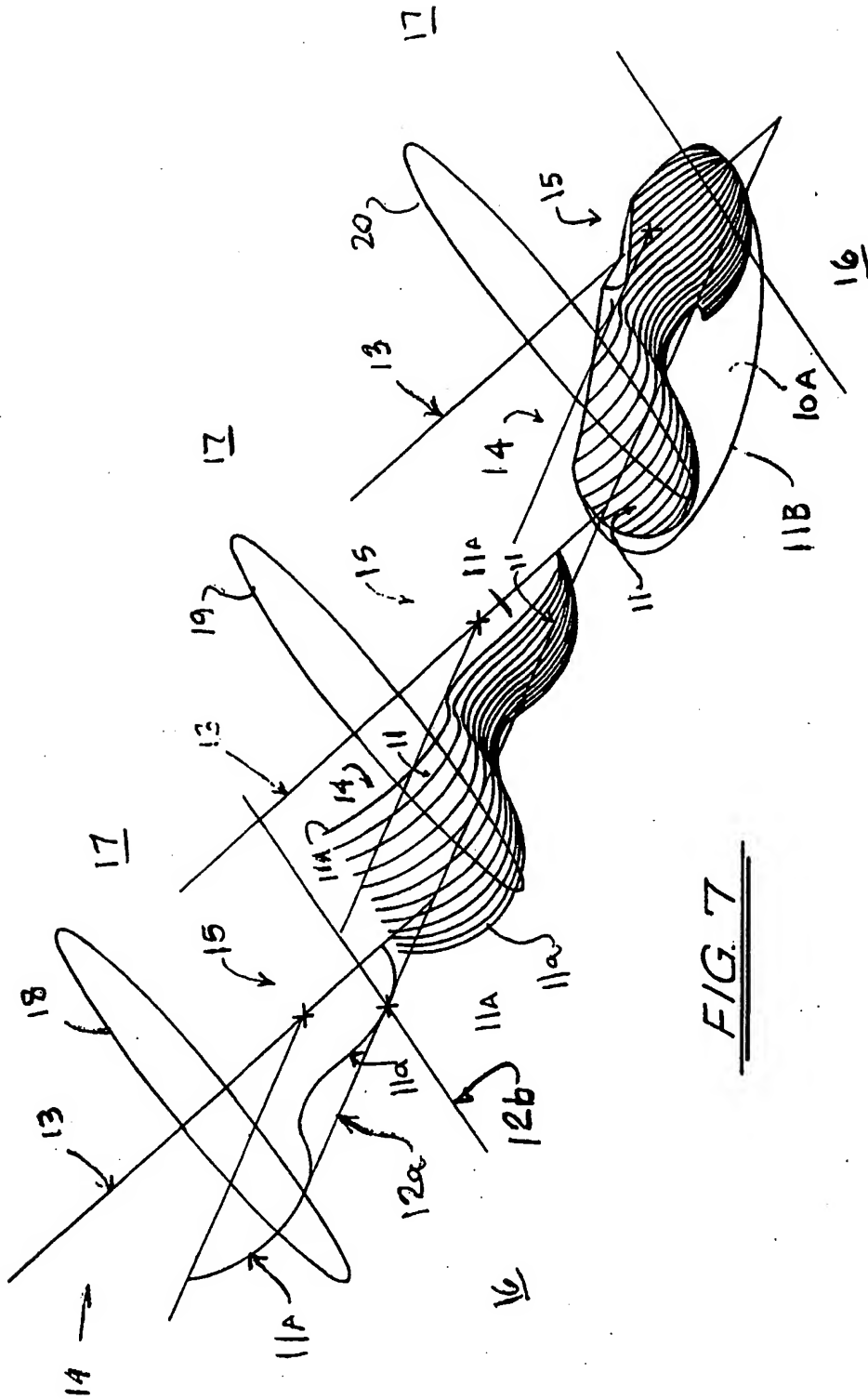


FIG. 7

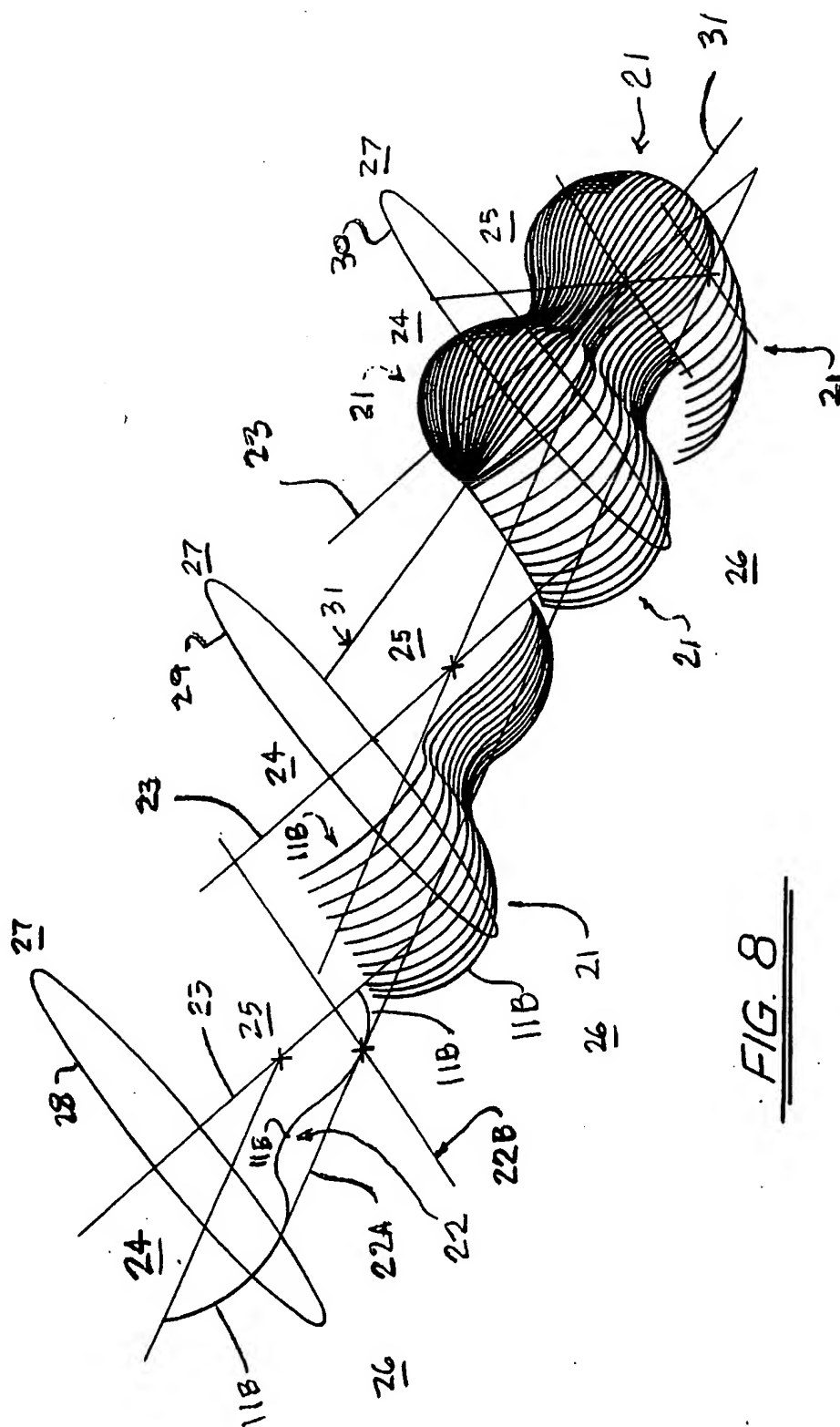


FIG. 8

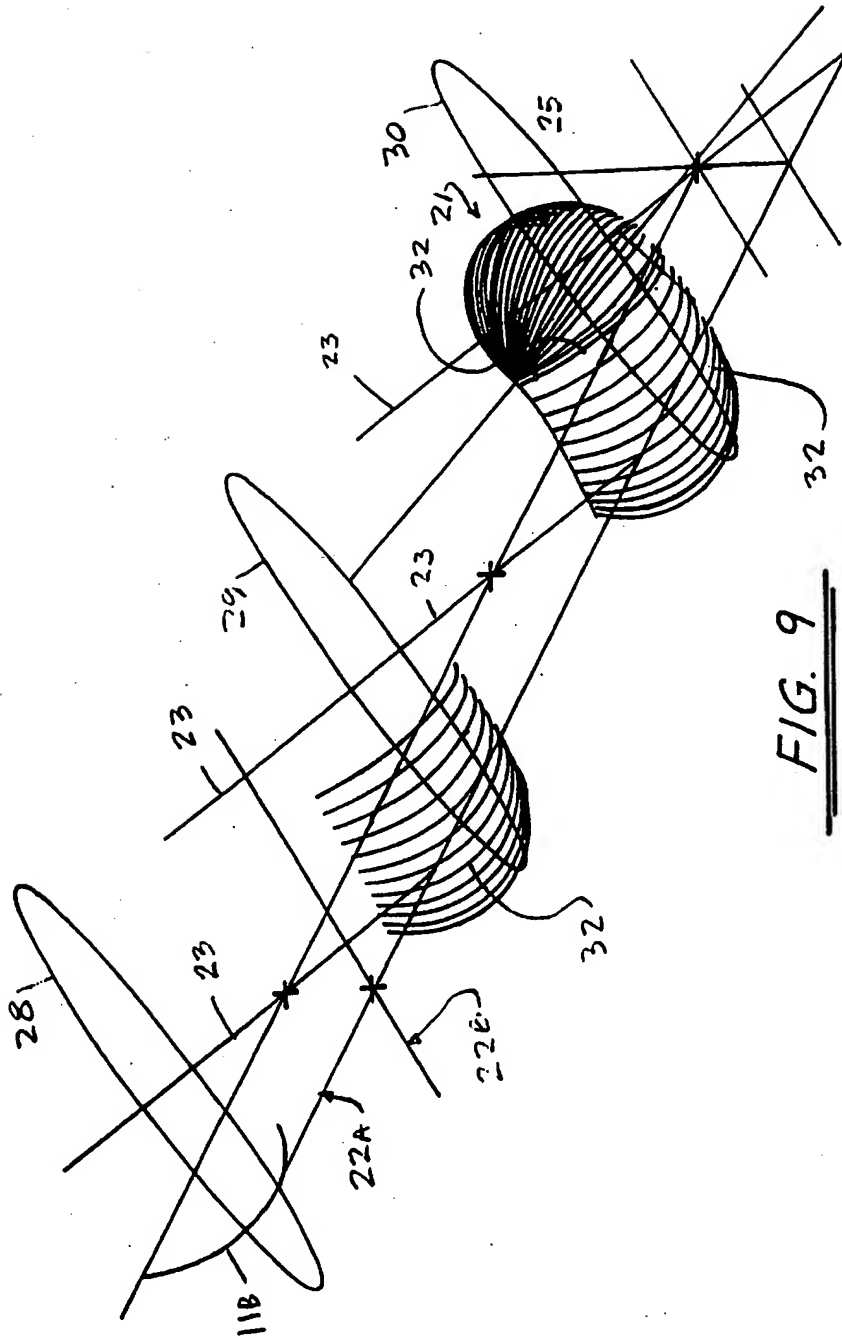


FIG. 9

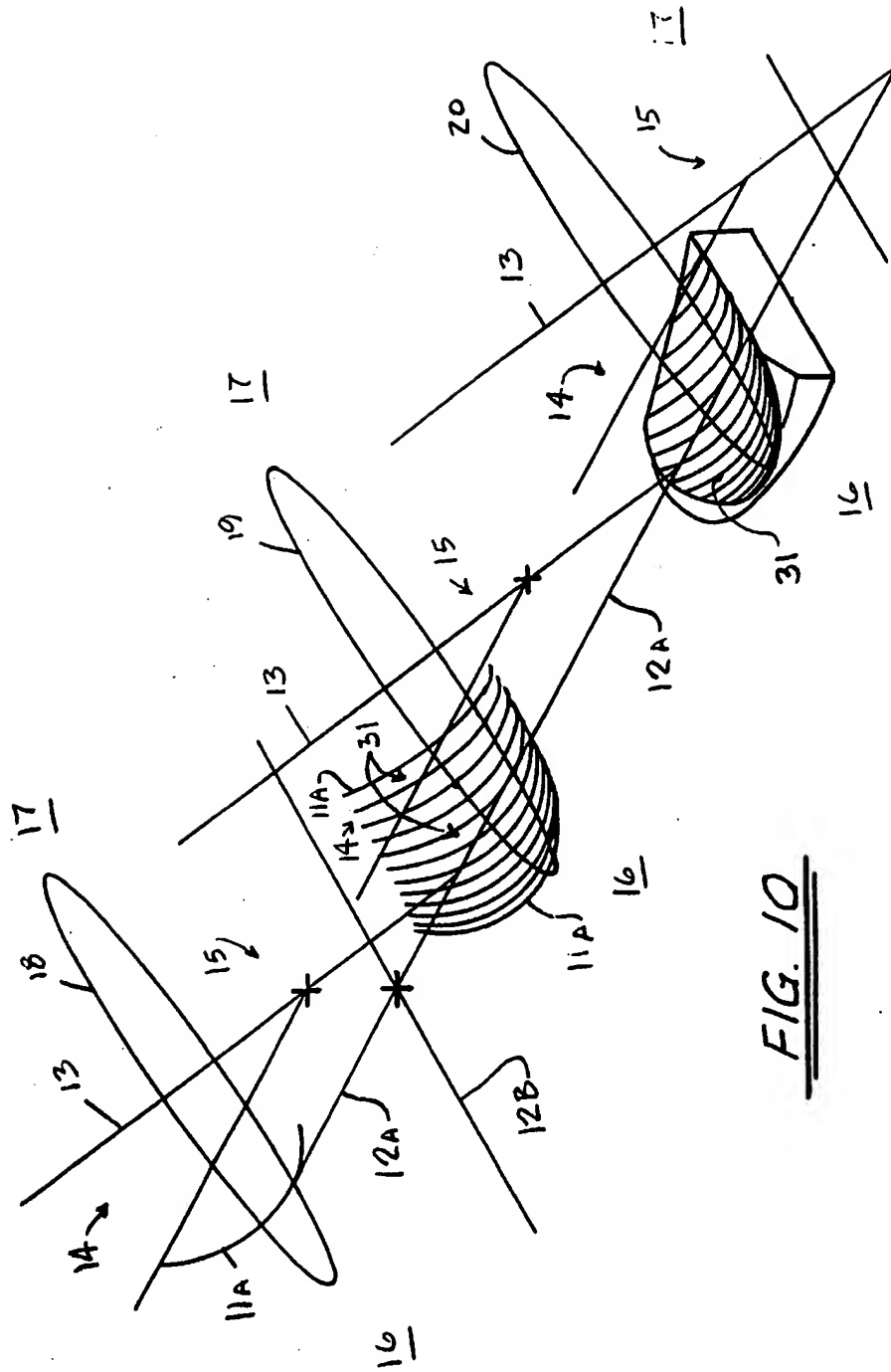


FIG. 10

